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PTO TRANSMITTAL FORM JUL 22 2005 PATENT & TRADEMARK OFFICE	Application Number	10/517,849	
	Filing Date	May 8, 2003 (I.A. filing date)	
	First Named Inventor	Werner Wessling	
	Art Unit		
	Examiner Name		
Total Number of Pages in This Submission		31	
		Attorney Docket Number	RO0957US (#90568)

ENCLOSURES (Check all that apply)		
<input checked="" type="checkbox"/> Fee Transmittal Form <input checked="" type="checkbox"/> Fee Attached <input checked="" type="checkbox"/> Amendment/Reply <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input type="checkbox"/> Extension of Time Request <input type="checkbox"/> Express Abandonment Request <input type="checkbox"/> Information Disclosure Statement <input type="checkbox"/> Certified Copy of Priority Document(s) <input type="checkbox"/> Reply to Missing Parts/Incomplete Application <input type="checkbox"/> Reply to Missing Parts under 37 CFR 1.52 or 1.53	<input type="checkbox"/> Drawing(s) <input type="checkbox"/> Licensing-related Papers <input type="checkbox"/> Petition <input type="checkbox"/> Petition to Convert to a Provisional Application <input type="checkbox"/> Power of Attorney, Revocation <input type="checkbox"/> Change of Correspondence Address <input type="checkbox"/> Terminal Disclaimer <input type="checkbox"/> Request for Refund <input type="checkbox"/> CD, Number of CD(s) _____ <input type="checkbox"/> Landscape Table on CD	<input type="checkbox"/> After Allowance Communication to TC <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <input type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief) <input type="checkbox"/> Proprietary Information <input type="checkbox"/> Status Letter <input checked="" type="checkbox"/> Other Enclosure(s) (please identify below): See the attached additional enclosures
Remarks		

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT			
Firm Name	D. Peter Hochberg Co., L.P.A.		
Signature			
Printed name	D. Peter Hochberg		
Date	July 19, 2005	Reg. No.	24,603

CERTIFICATE OF TRANSMISSION/MAILING			
I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below:			
Signature			
Typed or printed name	Sean Mellino	Date	July 20, 2005

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

**TRANSMITTAL FORM
(PTO/SB/21)**

ADDITIONAL ENCLOSURES

Application Number	10/517,849
Filing Date	May 8, 2003 (I.A. filing date)
First Named Inventor	Werner Wessling
Art Unit	
Examiner Name	
Attorney Docket Number	RO0957US (#90568)

Letter

IPER translation

chemical reference book disclosures

copy of Notification of Missing Requirements

Declaration

Second Preliminary Amendment

Effective on 12/08/2004.
Fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818).

FEE TRANSMITTAL

For FY 2005

☐ Applicant claims small entity status. See 37 CFR 1.27

Complete if Known

Application Number 10/517,849
Filing Date 8 May 2003 (I.A. filing date)
First Named Inventor Werner Wessling
Examiner Name
Art Unit
Attorney Docket No. RO0957US (#90568)

TOTAL AMOUNT OF PAYMENT (\$ 530.00)

METHOD OF PAYMENT (check all that apply)

☐ Check ☒ Credit Card ☐ Money Order ☐ None ☐ Other (please identify):
☒ Deposit Account Deposit Account Number: 08-2441 Deposit Account Name: D. Peter Hochberg Co., L.P.A.

For the above-identified deposit account, the Director is hereby authorized to: (check all that apply)

☐ Charge fee(s) indicated below ☐ Charge fee(s) indicated below, except for the filing fee
☒ Charge any additional fee(s) or underpayments of fee(s) under 37 CFR 1.16 and 1.17 ☒ Credit any overpayments

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

FEE CALCULATION

1. BASIC FILING, SEARCH, AND EXAMINATION FEES

Application Type	FILING FEES		SEARCH FEES		EXAMINATION FEES		Fees Paid (\$)
	Fee (\$)	Small Entity Fee (\$)	Fee (\$)	Small Entity Fee (\$)	Fee (\$)	Small Entity Fee (\$)	
Utility	300	150	500	250	200	100	0.00
Design	200	100	100	50	130	65	
Plant	200	100	300	150	160	80	
Reissue	300	150	500	250	600	300	
Provisional	200	100	0	0	0	0	

2. EXCESS CLAIM FEES

Fee Description	Fee (\$)	Small Entity Fee (\$)
Each claim over 20 (including Reissues)	50	25
Each independent claim over 3 (including Reissues)	200	100
Multiple dependent claims	360	180

Total Claims 28** Extra Claims Fee (\$)

32 ~~28~~ HP = 4 x 50.00 = 200.00

HP = highest number of total claims paid for, if greater than 20.

Indep. Claims** Extra Claims Fee (\$)

6 ~~2~~ HP = 1 x 200.00 = 200.00

HP = highest number of independent claims paid for, if greater than 3.

Multiple Dependent Claims
Fee (\$)

3. APPLICATION SIZE FEE

If the specification and drawings exceed 100 sheets of paper (excluding electronically filed sequence or computer listings under 37 CFR 1.52(e)), the application size fee due is \$250 (\$125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).

Total Sheets Extra Sheets Number of each additional 50 or fraction thereof Fee (\$)

- 100 = / 50 = (round up to a whole number) x 250.00 = 0.00

4. OTHER FEE(S)

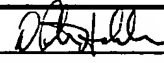
Non-English Specification, \$130 fee (no small entity discount)

Other (e.g., late filing surcharge): Late oath/declaration surcharge

Fees Paid (\$)

130.00

SUBMITTED BY

Signature  Registration No. 24,603 Telephone 216-771-3800
Name (Print/Type) D. Peter Hochberg Date July 19, 2005

This collection of information is required by 37 CFR 1.136. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 30 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

CERTIFICATE OF MAILING

I hereby certify that this document is being deposited with the United States Postal Service as First Class mail in an envelope addressed: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450, on the date noted below:

Date: July 20, 2005

Sean Mellino
Sean Mellino

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Werner Wessling

Serial No. : 10/517,849 (Conf. No. 1323)

International App. No. : PCT/EP03/04807

I.A. Filing Date : May 8, 2003

Title : FILM-SHAPED, MUCOADHESIVE
ADMINISTRATION FORMS FOR
ADMINISTRATION OF CANNABIS
AGENTS

Examiner :

Art Unit :

Attorney Docket : RO0957US (#90578)

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Response to Notification of Missing Requirements under 35 U.S.C. 371

Sir:

In response to the Notification of Missing Requirements issued on June 27, 2005, a declaration executed by the inventor is submitted herewith. A copy of the Notification of Missing Requirements and the requisite fee are also enclosed herewith.

10/12/2005 10:00:00 AM 00000000 00000000

10/12/2005 10:00:00 AM 00000000 00000000

10/12/2005 10:00:00 AM 00000000 00000000

Date: July 19, 2005

Respectfully submitted,

By: D. Peter Hochberg
Reg. No. 24,603



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
 United States Patent and Trademark Office
 Address: COMMISSIONER FOR PATENTS
 P.O. Box 1450
 Alexandria, Virginia 22313-1450
 www.uspto.gov

U.S. APPLICATION NUMBER NO.	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
10/517,849	Werner Wessling	R00957US (#90568)

INTERNATIONAL APPLICATION NO.

PCT/EP03/04807

I.A. FILING DATE	PRIORITY DATE
------------------	---------------

05/08/2003

06/14/2002

D Peter Hochberg
 D Peter Hochberg Co
 1940 E 6th Street
 6th Floor
 Cleveland, OH 44114

CONFIRMATION NO. 1323

371 FORMALITIES LETTER



OC000000016386081

Date Mailed: 06/27/2005

NOTIFICATION OF MISSING REQUIREMENTS UNDER 35 U.S.C. 371 IN THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US)

The following items have been submitted by the applicant or the IB to the United States Patent and Trademark Office as a Designated / Elected Office (37 CFR 1.495).

- Copy of the International Application filed on 12/14/2004
- Copy of the International Search Report filed on 12/14/2004
- Copy of IPE Report filed on 12/14/2004
- Copy of Annexes to the IPER filed on 12/14/2004
- Preliminary Amendments filed on 12/14/2004
- Information Disclosure Statements filed on 12/14/2004
- Request for Immediate Examination filed on 12/14/2004
- Copy of references cited in ISR filed on 12/14/2004
- U.S. Basic National Fees filed on 12/14/2004
- Substitute Specification filed on 12/14/2004

The following items **MUST** be furnished within the period set forth below in order to complete the requirements for acceptance under 35 U.S.C. 371:

- Oath or declaration of the inventors, in compliance with 37 CFR 1.497(a) and (b), identifying the application by the International application number and international filing date.

- \$130 Surcharge for providing the oath or declaration later than 30 months from the priority date (37 CFR 1.492(e)) is required.

SUMMARY OF FEES DUE:

Total additional fees required for this application is \$130 for a Large Entity:

- \$130 Late oath or declaration Surcharge.

ALL OF THE ITEMS SET FORTH ABOVE MUST BE SUBMITTED WITHIN TWO (2) MONTHS FROM THE DATE OF THIS NOTICE OR BY 32 MONTHS FROM THE PRIORITY DATE FOR THE APPLICATION, WHICHEVER IS LATER. FAILURE TO PROPERLY RESPOND WILL RESULT IN ABANDONMENT.

The time period set above may be extended by filing a petition and fee for extension of time under the provisions of 37 CFR 1.136(a).

Applicant is reminded that any communications to the United States Patent and Trademark Office must be mailed to the address given in the heading and include the U.S. application no. shown above (37 CFR 1.5)

*A copy of this notice **MUST** be returned with the response.*

PATRICIA A BOOKER

Telephone: (703) 308-9140 EXT 204

PART 1 - ATTORNEY/APPLICANT COPY

U.S. APPLICATION NUMBER NO.	INTERNATIONAL APPLICATION NO.	ATTY. DOCKET NO.
10/517,849	PCT/EP03/04807	R00957US (#90568)

FORM PCT/DO/EO/905 (371 Formalities Notice)

22 JUL 2005 #5

CERTIFICATE OF MAILING

I hereby certify that this document is being deposited with the United States Postal Service as First Class mail in an envelope addressed: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450, on the date noted below:

Date: July 20, 2005

Sean Mellino
Sean Mellino

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Werner Wessling

Serial No. : 10/517,849 (Conf. No. 1323)

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ADMINISTRATION FORMS FOR
ADMINISTRATION OF CANNABIS
AGENTS

Examiner/Art Unit :

Attorney Docket : RO0957US (#90578)

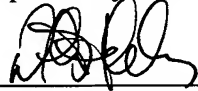
Commissioner for Patents
P O Box 1450
Alexandria, Virginia, 22313-1450

LETTER

Dear Sir:

In order to supplement the filing documents of the above-referenced U.S. national phase patent application, enclosed herewith is a translation of the International Preliminary Examination Report (PCT/IPEA/409). Also enclosed are reference book disclosures of cannabis and tetrahydrocannabinol (THC) set forth in the present application.

Respectfully submitted,



D. Peter Hochberg
Reg. No. 24,603

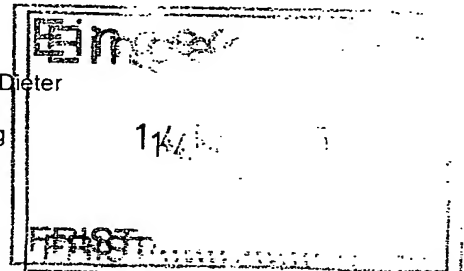
D. Peter Hochberg Co., L.P.A.
1940 E.6th Street - 6th Floor
Cleveland, OH 44114-2294
(216) 771-3800

From the INTERNATIONAL BUREAU

PCTNOTIFICATION OF TRANSMITTAL
OF COPIES OF TRANSLATION
OF THE INTERNATIONAL PRELIMINARY
EXAMINATION REPORT

(PCT Rule 72.2)

To:

FLACCUS, Rolf-Dieter
Bussardweg 10
50389 Wesseling
ALLEMAGNE

Date of mailing (day/month/year) 10 March 2005 (10.03.2005)	
Applicant's or agent's file reference LTS 2002/005 PCT	IMPORTANT NOTIFICATION
International application No. PCT/EP2003/004807	International filing date (day/month/year) 08 May 2003 (08.05.2003)
Applicant LTS LOHMANN THERAPIE-SYSTEME AG et al	

1. Transmittal of the translation to the applicant.

The International Bureau transmits herewith a copy of the English translation made by the International Bureau of the international preliminary examination report established by the International Preliminary Examining Authority.

2. Transmittal of the copy of the translation to the elected Offices.

The International Bureau notifies the applicant that copies of that translation have been transmitted to the following elected Offices requiring such translation:

CA, CN, KR, RU

The following elected Offices, having waived the requirement for such a transmittal at this time, will receive copies of that translation from the International Bureau only upon their request:

AU, BR, EP, IL, IN, JP, MX, NZ, PH, PL, US, ZA

3. Reminder regarding translation into (one of) the official language(s) of the elected Office(s).

The applicant is reminded that, where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report.

It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned (Rule 74.1). See Volume II of the PCT Applicant's Guide for further details.

The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland

Authorized officer

Ellen Moyse

Facsimile No. +41 22 740 14 35

Facsimile No. +41 22 338 89 75

Translation

PATENT COOPERATION TREATY

PCT/EP2003/004807



PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference LTS 2002/005 PCT	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/EP2003/004807	International filing date (day/month/year) 08 May 2003 (08.05.2003)	Priority date (day/month/year) 14 June 2002 (14.06.2002)
International Patent Classification (IPC) or national classification and IPC A61K 9/00		
Applicant LTS LOHMANN THERAPIE-SYSTEME AG		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of <u>5</u> sheets, including this cover sheet. <input checked="" type="checkbox"/> This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT). These annexes consist of a total of <u>6</u> sheets.
3. This report contains indications relating to the following items: I <input checked="" type="checkbox"/> Basis of the report II <input type="checkbox"/> Priority III <input checked="" type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability IV <input type="checkbox"/> Lack of unity of invention V <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement VI <input type="checkbox"/> Certain documents cited VII <input type="checkbox"/> Certain defects in the international application VIII <input type="checkbox"/> Certain observations on the international application

Date of submission of the demand 06 September 2003 (06.09.2003)	Date of completion of this report 28 September 2004 (28.09.2004)
Name and mailing address of the IPEA/EP Facsimile No.	Authorized officer Telephone No.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/EP2003/004807

I. Basis of the report

1. With regard to the elements of the international application:*

- ☐ the international application as originally filed
- ☒ the description:
pages 1-8, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____
- ☒ the claims:
pages _____, as originally filed
pages _____, as amended (together with any statement under Article 19
pages _____, filed with the demand
pages 1-16, filed with the letter of 31 March 2004 (31.03.2004)
- ☐ the drawings:
pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____
- ☐ the sequence listing part of the description:
pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language _____ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/fig _____

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rule 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/EP2003/004807

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application.

☒ claims Nos. 13-16

because:

☒ the said international application, or the said claims Nos. 13-16
relate to the following subject matter which does not require an international preliminary examination (*specify*):

SEE SUPPLEMENTAL SHEET

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. _____
are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. _____ are so inadequately supported
by the description that no meaningful opinion could be formed.

☐ no international search report has been established for said claims Nos. _____.

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the standard.

☐ the computer readable form has not been furnished or does not comply with the standard.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/EP 03/04807

Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: III.1.

Claims 13-16 relate to subject matter which, in the opinion of this Authority, falls under PCT Rule 67.1(iv). Consequently, no expert opinion has been established in respect of the industrial applicability of the subject matter of said claims (PCT Article 34(4)(a)(i)).

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/EP 03/04807

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	4 - 8	YES
	Claims	1 - 3, 9 - 16	NO
Inventive step (IS)	Claims		YES
	Claims	1 - 16	NO
Industrial applicability (IA)	Claims	1 - 12	YES
	Claims		NO

2. Citations and explanations

Reference is made to the following document:

D1: WO 99/15210 A

1 - Clarity

The subject matter of independent claims 1 and 9 does not satisfy the requirements of PCT Article 6, since the terms "cannabis extract" and "cannabis oil" are vague and unclear. Neither the claims nor the description defines what composition such an extract or oil should have or how it should be obtained. For this reason, any material obtained from cannabis or any mixtures of such ingredients could be considered "cannabis extract" or "cannabis oil". Therefore, a person skilled in the art cannot determine the scope of protection for claims 1 and 9.

2 - Novelty

Notwithstanding the lack of clarity mentioned above, the subject matter of claims 1-3 and 9-16 additionally lacks novelty within the meaning of PCT Article 33(2).

1 - Document D1 discloses a film-like bioadhesive composition for the topical administration of active substances (claims 1, 16, 22 and 23; page 1, first paragraph). Tetrahydrocannabinols are mentioned in the list of "antinauseant drugs" (see pages 31 and 32, point

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/EP 03/04807

50), and the subject matter of claims 1-3 and 9-16 is thus not novel over D1.

2 - The subject matter of claims 4-8 is considered novel.

3 - Inventive Step

1 - In the absence of novelty, an inventive step cannot be acknowledged for the subject matter of claims 1-3 and 9-16 (PCT Article 33(3)).

2 - Dependent claims 4-8 apparently do not contain any features that could substantiate an inventive step, since the application does not indicate any unexpected effects or properties of the subject matter of these claims.

4 - Industrial Applicability

The subject matter of claims 1-12 satisfies the requirements of PCT Article 33(4) (see also Box III).